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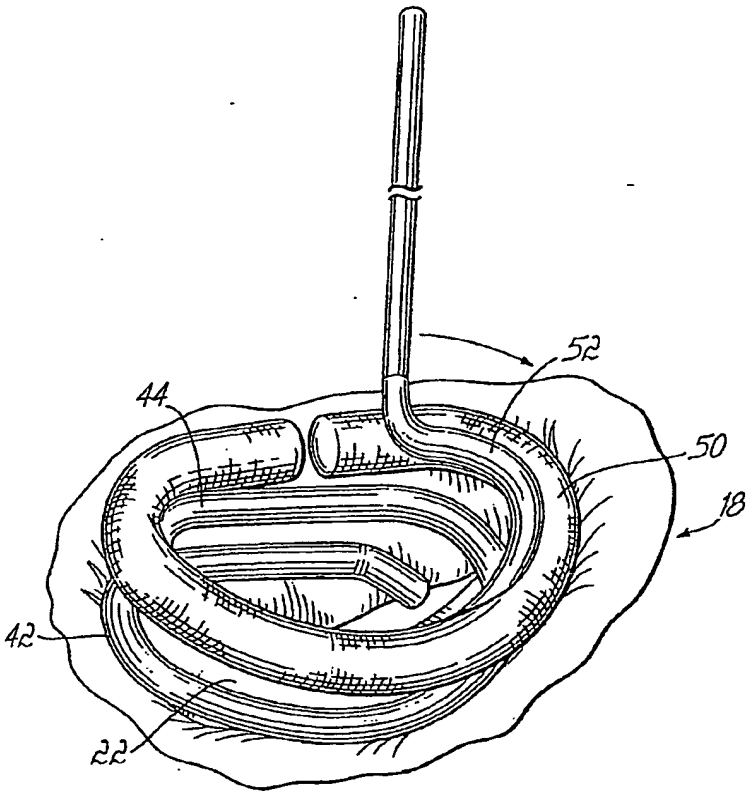
(54) Title: ANNULOPLASTY INSTRUMENT



(57) Abstract: A device for repairing a heart valve comprises an implantation instrument. The implantation instrument comprises a first support ring, and a second support ring connected to said first support ring to form a coiled configuration. The first support ring is configured to abut one side of the valve and the second support ring is configured to abut an opposite side of the valve to thereby trap a portion of the valve tissue therebetween. The device further comprises an annuloplasty implant adapted to be attached to the heart valve annulus in order to reshape the annulus and allow the leaflets to open and close properly. The annuloplasty implant is connected to the implantation instrument for insertion to the annulus.

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ANNULOPLASTY INSTRUMENT

Field of the Invention

The present invention generally relates to heart valve repair and replacement techniques and annuloplasty devices. More specifically, the invention relates to the replacement of heart valves.

Background of the Invention

Diseased mitral and tricuspid valves frequently need replacement or repair. The mitral and tricuspid valve leaflets or supporting chordae may degenerate and weaken or the annulus may dilate leading to valve leak (insufficiency). The leaflets and chords may become calcified and thickened rendering them stenotic (obstructing forward flow). Finally, the valve relies on insertion of the chordae inside the ventricle. If the ventricle changes in shape, the valve support may become non-functional and the valve may leak.

Mitral and tricuspid valve replacement and repair are traditionally performed with a suture technique. During valve replacement, sutures are spaced around the annulus (the point where the valve leaflet attaches to the heart) and then the sutures are attached to a prosthetic valve. The valve is lowered into position and when the sutures are tied, the valve is fastened to the annulus. The surgeon may remove all or part of the valve leaflets before inserting the prosthetic valve. In valve repair, a diseased valve is left in situ and surgical procedures are performed to restore its function. Frequently an annuloplasty ring is used to reduce the size of the annulus. The ring serves to reduce the diameter of the annulus and allow the leaflets to oppose each other normally. Sutures are used to attach a prosthetic ring to the annulus and to assist in plicating the annulus.

In general, the annuloplasty rings and replacement valves must be sutured to the valve annulus and this is time consuming and tedious. If the ring is severely malpositioned, then the stitches must be removed and the ring repositioned relative to the valve annulus during restitching. In other cases, a less than optimum annuloplasty may be tolerated by the surgeon rather than lengthening the time of the surgery to restitch the ring.

During heart surgery, a premium is placed on reducing the amount of time used to replace and repair valves as the heart is frequently arrested and without perfusion. It would therefore be very useful to have a method to efficiently attach a prosthesis into the mitral or tricuspid valve position.

Summary of the Invention

It is an object of the invention to provide a more reliable and more easily accomplished valve repair or replacement. It is a specific object of the invention to facilitate insertion of an annuloplasty implant.

These and other objects of the invention are accomplished by means of a device and a method according to the independent claims. Preferred embodiments of the invention are apparent from the dependent claims.

Thus, according to a first aspect of the invention, a replacement valve device for replacing a heart valve of a patient is provided. The device comprises an implantation instrument, which comprises a first support ring, and a second support ring connected to said first support ring to form a coiled configuration. The first support ring is configured to abut one side of an area of valve tissue and the second support ring is configured to abut an opposite side of the area of the valve tissue to thereby trap the valve tissue therebetween. The device further comprises a replacement valve adapted to be attached to the valve tissue and including at least one valve element for allowing and preventing blood flow

through the valve position. The replacement valve is coupled to the implantation instrument for insertion into the patient.

The invention also provides a method of replacing a heart valve of a patient. The method comprises inserting an implantation instrument comprising a first and a second support ring connected to each other to form a coiled configuration and a replacement valve being attached to the second support ring into the patient, said instrument being inserted such that valve tissue is trapped between the first and second support rings, attaching the replacement valve to the valve tissue, and removing the implantation instrument.

The implantation instrument provides a possibility to easily introduce the device into position in a heart valve. The implantation instrument anchors the device at the heart valve position such that the replacement valve may be attached to valve tissue that is fixated by the implantation instrument. The replacement valve may be arranged to be attached to the valve tissue by means of staples. This implies that the replacement valve may be easily attached to the valve tissue, when the implantation instrument fixates the valve tissue.

The replacement valve may be coupled to the second support ring in a removable manner. This implies that the replacement valve may be detached from the implantation instrument after the replacement valve has been attached to the valve tissue. The implantation instrument may thereafter be removed from the patient. The annuloplasty implant may be attached to the second support ring by means of a removable suture. The suture may be cut in order to detach the annuloplasty implant from the implantation instrument.

The first and second support rings may be axially moveable with respect to each other. This facilitates insertion of the annuloplasty instrument. The rings may initially be applied on opposite sides of valve tissue

and may thereafter be drawn towards each other in order to trap valve tissue therebetween. Thus, there is no friction between the rings and valve tissue during placement of the rings on opposite sides of the valve.

The step of inserting may comprise inserting a first end of the first support ring through a portion of the valve tissue, rotating the implantation instrument to position the first support ring on a first side of the valve, and positioning the second support ring on an opposite second side of the valve. The first and second support ring are thus easily applied on opposite sides of the valve.

According to a second aspect of the invention, a device is provided for repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing blood flow through a patient's heart. The device comprises an implantation instrument, which comprises a first support ring, and a second support ring connected to the first support ring to form a coiled configuration. The first support ring is configured to abut one side of the valve and the second support ring is configured to abut an opposite side of the valve to thereby trap a portion of the valve tissue, that is, annulus tissue and/or leaflet tissue, therebetween. The device further comprises an annuloplasty implant adapted to be attached to the heart valve annulus in order to reshape the annulus and allow the leaflets to open and close properly.

The implantation instrument is applied to the heart valve in a much easier manner than conventionally utilized annuloplasty rings. By means of the implantation instrument it is possible to fixate the valve annulus and primarily reshape it. This primary reshaping of the valve annulus facilitates attachment of the annuloplasty implant to the valve annulus. There is merely a need for a slight further reshaping of the valve annulus by the attachment of the annuloplasty implant in order to

achieve the desired shape of the valve annulus. Since the attachment of the annuloplasty implant need not dramatically change the shape of the valve annulus, the possibility of correctly positioning the annuloplasty implant is greatly increased. This implies that there is a very slim risk that the annuloplasty implant will need to be repositioned. Further, by means of the device the desired reshaping of the valve annulus may in most cases be achieved.

The invention contemplates various embodiments of the device, including embodiments for catheter-based surgery and embodiments for open heart surgery.

The first and second support rings may have generally triangular-shaped cross sections with flat sides opposing one another and trapping valve tissue therebetween.

At least the opposed surfaces of the first and second support rings may be roughened, such as by the use of fabric, coatings, knurling or the like to facilitate better engagement and retention of the support rings on the valve tissue. The opposed surfaces may be roughened in a pattern extending along the longitudinal direction of the rings. This implies that the roughened surface will serve to prevent slippage of tissue through the ring while presenting a low friction for the ring to be turned into position abutting the valve. The implantation instrument may have an inherent shape where the first and second rings contact or nearly contact each other. Thus, the implantation instrument will present a spring force pushing the first and second rings towards each other. The spring force will make the first and second rings fixating valve tissue between them.

Preferably, the first and second support rings are formed integrally from a coiled rod, such as a metallic rod, with one end of the rod formed as a leading end and one end formed as a trailing end. These ends may be bent in opposite directions so that the leading end may be

directed through the valve tissue and the trailing end may be grasped by an appropriate surgical implement. A carrier may be used to rotate the implantation instrument into position on opposite sides of the valve annulus. As another alternative, the carrier may be coil-shaped and the implantation instrument may be rotated into place on only one side of the valve annulus similar to conventional rings. The carrier may also be rotated in opposite direction for withdrawing the implantation instrument. The first and second support rings may be adjustable in diameter to allow adjustment of the valve annulus.

The annuloplasty implant may have an arcuate shape conforming to a desired arcuate shape of a portion of the annulus. The annuloplasty implant may then be attached to the portion of the valve annulus for reshaping the valve annulus. The desired reshaping of the valve annulus may be achieved by the annuloplasty implant reshaping only a portion of the valve annulus. Thus, the annuloplasty implant may be C- or U-shaped. The annuloplasty implant may alternatively have a ring-shape conforming to the desired shape of the annulus. The annuloplasty implant may thus be attached to the valve annulus forcing it to assume the desired shape.

The annuloplasty implant may be removably attached to the second support ring of the implantation instrument. The annuloplasty implant may then be detached from the implantation instrument after being attached to the valve annulus. The implantation instrument may thereafter be removed from the patient. The annuloplasty implant may be attached to the second support ring by means of a removable suture. The suture may be cut in order to detach the annuloplasty implant from the implantation instrument.

According to a third aspect of the invention, a kit is provided for repairing a heart valve comprised of valve tissue including an annulus and a plurality of

leaflets for allowing and preventing blood flow. The kit comprises an implantation instrument, which comprises a first support ring, and a second support ring connected to the first support ring to form a coiled configuration. The first support ring is configured to abut one side of the valve and the second support ring is configured to abut an opposite side of the valve to thereby trap a portion of the valve tissue therebetween. The kit further comprises an annuloplasty implant adapted to be attached to the heart valve annulus in order to reshape the annulus and allow the leaflets to open and close properly.

The annuloplasty implant need not be attached to the implantation instrument for being inserted to the heart valve. The implantation instrument may provide the primary reshaping of the valve annulus. The annuloplasty implant may then be separately inserted to permanently reshape the valve annulus. The correct positioning of the annuloplasty implant is now easily achieved since the primary reshaping of the valve annulus provided by the implantation instrument clearly indicates how the annuloplasty implant should be attached to the valve annulus.

According to a fourth aspect of the invention, a method is provided for repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing blood flow. The method comprises inserting an implantation instrument comprising a first and a second support ring connected to each other to form a coiled configuration, said instrument being inserted such that valve tissue is trapped between the first and second support rings, attaching an annuloplasty implant to the annulus in order to reshape it, and removing the implantation instrument.

The step of inserting the instrument may comprise temporarily reshaping the annulus to facilitate attachment of the annuloplasty implant to the annulus.

Thus, the implantation instrument will guide the positioning of the annuloplasty implant.

The step of inserting may further comprise inserting a first end of the first support ring through a portion of the valve tissue, rotating the implantation instrument to position the first support ring on a first side of the valve, and positioning the second support ring on an opposite second side of the valve. The first and second support ring are thus easily applied on opposite sides of the valve.

Various additional objectives, advantages and features of the invention will become more readily apparent to those of ordinary skill in the art upon review of the detailed description of the illustrative embodiments.

Brief Description of the Drawings

Fig. 1 schematically illustrates a patient with a heart shown in cross section and a device of the present invention schematically illustrated as supporting the mitral valve.

Fig. 1A is a cross sectional view of the left ventricle showing the mitral valve and a device according to a first embodiment of the invention in perspective.

Fig. 2 is a perspective view of a device according to an embodiment of the invention.

Fig. 3 is a cross sectional view of the device in Fig. 2.

Figs 4a-b are perspective views of a device according to another embodiment of the invention. Fig. 4b is an enlarged view of the portion marked IVB in Fig. 4a.

Fig. 5 is a perspective view of a device according to a second embodiment of the invention.

Figs 6a-b are partially sectioned perspective views of the mitral valve and the device of the invention during implantation of an annuloplasty implant of the device.

Fig. 7 is a partially sectioned perspective view showing the device of the invention when the implantation instrument has been turned into position.

Fig. 8 is a cross-sectional view illustrating primary reshaping of the valve.

Fig. 9 is a partially sectioned perspective view showing the device when the annuloplasty implant is being attached to the valve annulus.

Fig. 10 is a perspective view showing the device after implantation is completed.

Fig. 11 is a partially sectioned perspective view showing the device according to the second embodiment when the implantation instrument has been turned into position.

Fig. 12 is a partially sectioned perspective view showing the device when the replacement valve is being attached to the valve annulus.

Fig. 13 is a perspective view showing the device according to the second embodiment after implantation is completed.

Detailed Description of the Preferred Embodiments

Fig. 1 illustrates a patient 10 having a heart 12 shown in cross section including a left ventricle 14 and a right ventricle 16. The concepts of the present invention are suitable to be applied, for example, to a mitral valve 18 which supplies blood into left ventricle 14. Mitral valve 18, as better shown in Fig. 1A, includes an annulus 20 and a pair of leaflets 22, 24 which selectively allow and prevent blood flow into left ventricle 14. It will be appreciated that the term annulus tissue is used extensively throughout this disclosure in reference to the drawings, however, the inventive principles are equally applicable when referring to other valve tissue such as leaflet tissue or other attached vessel tissue. Leaflets 22, 24 are supported for coaptation by chordae tendinae or chords

26, 28 extending upwardly from respective papillary muscles 30, 32. Blood enters left ventricle 14 through mitral valve 18 and is expelled during subsequent contraction of heart 12 through aortic valve 34. It will be appreciated that the present invention is applicable to tricuspidal heart valves as well.

A preferred device of the present invention is shown in Figs 2 and 3. The device comprises an implantation instrument 40 which comprises a first and a second support ring 42, 44 assuming a coiled configuration in the form of a spiral or keyring-type configuration. Any suitable medical grade material(s), such as medical grade metals or plastics, may be used to form the implantation instrument 40. The device is shown in cross section in Fig. 3. The implantation instrument 40 has a traditional cross sectional shape associated with a keyring. In this embodiment flat, opposed surfaces 45 are arranged to trap valve annulus tissue 20 therebetween. The opposed surfaces 45 may also be roughened in order to improve engagement with the valve annulus 20.

As illustrated in Figs 4a-b, the first and second support rings 42, 44 may be axially moved in relation to each other. Thus, the support rings 42, 44 may be inserted on opposite sides of a heart valve and thereafter be drawn towards each other for trapping valve annulus tissue 20 between them. The first support ring 42 is connected to the second support ring 44 via a rod 46. The rod 46 is attached to the first support ring 42 and is connected to a stem 47 that extends from the second support ring 44 out of the patient in which the implantation instrument is inserted. The rod 46 is slidably connected to the stem 47 for moving the first support ring 42 in axial relation to the second support ring 44. The rod 46 is angled in order to allow the first and second support rings 42, 44 to be arranged in close relationship to each other. The rod 46 comprises an eye 48 at its angle. The eye 48 may receive a string 49

extending out of the patient. The implantation instrument 40 may be inserted into the patient in the configuration shown in Fig. 4a and in greater detail in Fig. 4b. The instrument 40 may then be rotated into position with the support rings 42, 44 on opposite sides of a hear valve. The rotational movement will not be hindered by friction between the support rings 42, 44 and annulus tissue 20 since the support rings 42, 44 are spaced from each other. When the support rings 42, 44 have been placed at opposite sides of the heart valve, the first support ring 42 may be drawn towards the second support ring 44 by pulling the string 49, as indicated by arrow A.

An annuloplasty implant 50 is attached to the second support ring 44 of the implantation instrument 40, by means of sutures or clips. The annuloplasty implant 50 may be any type of annuloplasty ring, such as the CG Future™ Annuloplasty System manufactured by Medtronic, Inc., the SJM Tailor® Annuloplasty Ring or the SJM Tailor® Flexible Annuloplasty Band manufactured by St. Jude Medical, Inc., the Sovering™ manufactured by Sorin Group, the Carpentier-McCarthy-Adams IMR ETlogix Annuloplasty Ring® or the Carpentier-Edwards Classic Annuloplasty Ring® manufactured by Edwards Lifesciences Corporation, which annuloplasty ring may form a complete ring-shape or an arcuate shape. The annuloplasty implant 50 is adapted to be attached to the valve annulus 20 by means of suture threads, as will be explained in further detail below. The annuloplasty implant 50 has a shape conforming to a desired shape of the valve annulus 20. Thus, when attached to the valve annulus 20, the annuloplasty implant 50 will reshape the valve annulus 20 to a desired shape. The annuloplasty implant 50 is non-stretchable lengthwise, which implies that when attached to the valve annulus it will not allow dilatation of the annulus. However, the annuloplasty implant may be flexible to change its shape while maintaining its length to allow the normal movements of the valve annulus 20

during a heart cycle. The annuloplasty implant 50 may have sections of differing rigidity and flexibility to comply with the normal movements of the valve annulus 20 during the heart cycle.

Alternatively, as illustrated in Fig. 5, a replacement valve 70 is attached to the second support ring 44 of the implantation instrument 40, by means of sutures or clips. The replacement valve 70 may be conventional or of any desired design. The replacement valve 70 may have movable flaps 72, 74 for providing a valve function. The replacement valve 70 further has an outer portion 76 at least partly surrounding the flaps 72, 74 and arranged to be attached to annulus tissue 20. The outer portion 76 may be a cuff or flange arranged to receive a suture or staple or any other means for attaching the outer portion 76 to the annulus tissue 20. The implantation instrument 40 is arranged to fixate the annulus tissue 20 for facilitating attachment of the replacement valve 70 to the annulus tissue 20.

Referring now to Figs 6-9, a method for repairing a heart valve by means of the device will be described. First, access to the heart valve is achieved by conventional techniques, including arresting the heart and opening the chest. In Fig. 6a, the device is shown when being inserted to the mitral valve 18. The implantation instrument 40 is being carried on a coil-shaped carrier 52, which is connected to a stem for remote control of the positioning of the carrier 52. An end of the first support ring 42 is brought to a corner of the opening between the leaflets 22, 24 of the mitral valve 18, as shown in Fig. 6b. The end is led through the opening and the coil-shaped carrier 52 is turned 360 degrees. Thus, the first support ring 42 will be rotated into place on one side of the valve 18, whereas the second support ring 44 is placed on the opposite side of the valve 18. In this way, the implantation instrument 40 is arranged in engagement with the valve 18, as shown in

Fig. 7. Alternatively, the implantation instrument 40 shown in Fig. 4a may be inserted. The implantation instrument 40 is rotated into position and, thereafter, the first support ring 42 is drawn towards the second support ring 44 so that the instrument 40 is arranged in engagement with the valve.

The leaflets 22, 24 may now be drawn towards each other through the pinch of the support rings 42, 44, as illustrated in Fig. 8. The leaflets are drawn through the pinch by means of a forceps instrument 54. The support rings 42, 44 may flex away from each other to allow drawing leaflets 22, 24 through the pinch and towards each other for preventing the leaflets 22, 24 to slip back. The valve annulus 20 may in this way be reshaped and be temporarily held in the new shape by means of the implantation instrument 40. The support rings 42, 44 may have roughened, opposed surfaces 45 to better keep the leaflets 22, 24 from slipping through the pinch and to hold the valve annulus 20 in its reshaped form.

The annuloplasty implant 50, which has been carried into position by means of the second support ring 44, may now be attached to the valve annulus 20 for achieving a permanent reshaping of the annlus 20. Since a primary reshaping has already been made, the positioning of the annuloplasty implant 50 is facilitated. The annuloplasty implant 50 is sutured to the valve annulus, as illustrated in Fig. 9, showing a completed suture 60 attaching the annuloplasty implant 50 to the valve annulus 20 and showing a suture 62 being performed. In this way, the annuloplasty implant 50 is firmly attached to the valve annulus 20 for keeping the valve annulus 20 in its reshaped form. The leaflets 22, 24 may also or alternatively be drawn towards each other through the pinch of the support rings 42, 44 during suturing of the annuloplasty implant 50.

When the annuloplasty implant 50 has been firmly attached to the valve annulus 20, the annuloplasty

implant 50 is released from the implantation instrument 40. The sutures holding the annuloplasty implant 50 attached to the second support ring 44 are cut in order to release the annuloplasty implant 50 from the implantation instrument 40. Now, the implantation instrument 40 may be withdrawn. The carrier 52 is turned 360 degrees in order to rotate the first support ring 42 to be retracted through the opening between the leaflets 22, 24. Thereafter, the carrier 52 with the implantation instrument 40 may be retracted from the patient. As shown in Fig. 10, the annuloplasty implant 50 is now left in the patient holding the valve annulus 20 in a reshaped form such as to function normally.

As an alternative, the implantation instrument 40 does not carry the annuloplasty implant 50. In this case, the implantation instrument 40 is inserted into position first. This positioning of the implantation instrument 40 may be performed as described above with reference to Figs 6-8. While the implantation instrument 40 is held in place maintaining the temporary reshaping of the valve annulus 20, the annuloplasty implant 50 may be inserted to the mitral valve by means of conventional techniques for inserting an annuloplasty ring using a carrier. The annuloplasty implant 50 is then sutured to the valve annulus in order to permanently keep the valve annulus 20 in its reshaped form. Thereafter, the carrier used for inserting the annuloplasty implant 50 and the implantation instrument 40 may be withdrawn leaving the annuloplasty implant 50 in the patient.

Referring now to Figs 11-13, a method for replacing a mitral valve by means of the device will be described. First, the native leaflets 22, 24 are cut off and removed, since the function of the leaflets 22, 24 will be replaced by a replacement valve 70. Then, the implantation instrument 40 may be inserted in a manner similar to the insertion described with reference to Figs

6a-6b above. As shown in Fig. 11, the implantation instrument is arranged in engagement with the valve 18.

The replacement valve 70, which has been carried into position by means of the second support ring 44, may now be attached to the valve annulus 20 for achieving a permanent replacement of the valve function. Since the support rings 42, 44 are arranged trapping annulus tissue 20 therebetween, the implantation instrument 40 will fix or stabilize the shape and position of the valve annulus 20. The support rings 42, 44 may have roughened, opposed surfaces 45 to better maintain the shape of the valve annulus 20. Thus, attachment of the replacement valve 70 to the valve tissue is facilitated as the tissue is held in position. For instance, the replacement valve 70 may be stapled to the valve tissue, while the implantation instrument 40 provides an anvil to the staple. Alternatively, the replacement valve 70 is sutured to the valve annulus, as illustrated in Fig. 12, showing a completed suture 80 attaching the replacement valve 70 to the valve annulus 20 and showing a suture 82 being performed. In this way, the replacement valve 70 is firmly attached to the valve annulus 20 for providing a valve function.

When the replacement valve 70 has been firmly attached to the valve annulus 20, the replacement valve 70 is released from the implantation instrument 40. The sutures holding the replacement valve 70 attached to the second support ring 44 are cut in order to release the replacement valve 70 from the implantation instrument 40. Now, the implantation instrument 40 may be withdrawn. The carrier 52 is turned 360 degrees in order to rotate the first support ring 42 to be retracted through the opening between the leaflets 22, 24. Thereafter, the carrier 52 with the implantation instrument 40 may be retracted from the patient. As shown in Fig. 13, the replacement valve 70 is now left in the patient replacing the function of the native valve.

It should be emphasized that the preferred embodiments described herein are in no way limiting and that many alternative embodiments are possible within the scope of protection defined by the appended claims.

For example, the access to the heart valve may be achieved endoscopically. In such case, the implantation instrument 40 and the annuloplasty implant 50 need to be inserted through a narrow tube (endoscope). This implies that the implantation instrument 40 and the annuloplasty implant 50 will need to be compressed during insertion in order to pass through the endoscope. The implantation instrument 40 needs to assume its proper shape after having been passed through the endoscope. Therefore, using an endoscopic approach, the implantation instrument 40 should preferably be formed from a shape memory material. This allows the implantation instrument 40 to be compressed and also to have a stable shape when being applied to the heart valve. Further, the annuloplasty implant 50 needs to be flexible in order to be compressed for the insertion through the endoscope.

CLAIMS

1. A replacement valve device for replacing a heart valve of a patient, the device comprising:

an implantation instrument, comprising:

a first support ring, and

a second support ring connected to said first support ring to form a coiled configuration, said first support ring configured to abut one side of an area of valve tissue and said second support ring configured to abut an opposite side of the area of the valve tissue to thereby trap the valve tissue therebetween, and

a replacement valve adapted to be attached to the valve tissue and including at least one valve element for allowing and preventing blood flow through the valve position, said replacement valve being coupled to the implantation instrument for insertion into the patient.

2. The device according to claim 1, wherein said replacement valve is coupled to said second support ring in a removable manner.

3. The device according to claim 2, wherein the replacement valve is attached to the second support ring by means of a removable suture.

4. The device according to claim 3, wherein the annuloplasty instrument is arranged to be withdrawn from the patient after the replacement valve has been attached to the valve tissue.

5. The device according to any one of claims 1-4, wherein the replacement valve is arranged to be attached to the valve tissue by means of staples.

6. The device according to any one of claims 1-5, wherein the first and second support rings are axially moveable with respect to each other.

7. A method of replacing a heart valve of a patient, the method comprising:

inserting an implantation instrument comprising a first and a second support ring connected to each other to form a coiled configuration and a replacement valve being attached to the second support ring into the patient, said instrument being inserted such that valve tissue is trapped between the first and second support rings,

attaching the replacement valve to the valve tissue, and

removing the implantation instrument.

8. The method according to claim 7, wherein the valve tissue is an annulus associated with a native heart valve.

9. The method according to claim 7 or 8, wherein the step of inserting comprises

inserting a first end of the first support ring through a portion of the valve tissue,

rotating the implantation instrument to position the first support ring on a first side of the valve, and

positioning the second support ring on an opposite second side of the valve.

10. A device for repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing blood flow, the device comprising:

an implantation instrument, comprising:

a first support ring, and

a second support ring connected to said first support ring to form a coiled configuration, said first support ring configured to abut one side of the valve and said second support ring configured to abut an opposite side of the valve to thereby trap a portion of the valve tissue therebetween, and

an annuloplasty implant adapted to be attached to the heart valve annulus in order to reshape the annulus and allow the leaflets to open and close properly, said

annuloplasty implant being connected to the implantation instrument for insertion to the annulus.

11. The device according to claim 10, wherein said first and second support rings have generally triangular-shaped cross sections.

12. The device according to claim 10 or 11, wherein said first and second support rings are formed from a shape memory alloy.

13. The device according to any one of claims 10-12, wherein the implantation instrument further comprises a material on at least one of said first and second support rings for reducing friction between the respective rings and the valve tissue in the longitudinal direction of the rings.

14. The device according to any one of claims 10-13, wherein opposed surfaces of said first and second support rings are roughened to facilitate engagement with the valve tissue.

15. The device according to claim 14, further comprising a coating of cushioning material on each of said opposite surfaces.

16. The device according to any one of claims 10-15, wherein each of said first and second support rings is formed from a fabric material.

17. The device according to any one of claims 10-15, wherein said support rings are formed from a flat plate material.

18. The device according to any one of claims 10-17, further comprising a carrier configured to carry said first and second support rings into position on opposite sides of the valve.

19. The device according to any one of claims 10-17, wherein said first and second support rings are adjustable in diameter to allow adjustment of the valve annulus.

20. The device according to claim 18, wherein the carrier has a coil-shaped element for allowing said first

and second support rings to be turned into position on said opposite sides of the valve tissue.

21. The device according to any one of claims 10-20, wherein the annuloplasty implant has a desired arcuate shape conforming to an arcuate shape of a portion of the annulus.

22. The device according to any one of claims 10-20, wherein the annuloplasty implant has a ring-shape conforming to the desired shape of the annulus.

23. The device according to any one of claims 10-22, wherein the annuloplasty implant is removably attached to the second support ring of the implantation instrument.

24. The device according to claim 23, wherein the annuloplasty implant is attached to the second support ring by means of a removable suture.

25. The device according to any one of claims 10-24, wherein the annuloplasty implant is arranged to be attached to the annulus by means of suture threads.

26. A kit for repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing blood flow, the kit comprising:

an implantation instrument, comprising:

a first support ring, and

a second support ring connected to said first support ring to form a coiled configuration, said first support ring configured to abut one side of the valve and said second support ring configured to abut an opposite side of the valve to thereby trap a portion of the valve tissue therebetween, and

an annuloplasty implant adapted to be attached to the heart valve annulus in order to reshape the annulus and allow the leaflets to open and close properly.

27. A method for repairing a heart valve comprised of valve tissue including an annulus and a plurality of leaflets for allowing and preventing blood flow, said method comprising:

inserting an implantation instrument comprising a first and a second support ring connected to each other to form a coiled configuration, said instrument being inserted such that valve tissue is trapped between the first and second support rings,

attaching an annuloplasty implant to the annulus in order to reshape it, and

removing the implantation instrument.

28. The method according to claim 27, wherein the step of inserting the instrument comprises temporarily reshaping the annulus to facilitate attachment of the annuloplasty implant to the annulus.

29. The method according to claim 27 or 28, wherein the step of inserting comprises

inserting a first end of the first support ring through a portion of the valve tissue,

rotating the implantation instrument to position the first support ring on a first side of the valve, and

positioning the second support ring on an opposite second side of the valve.

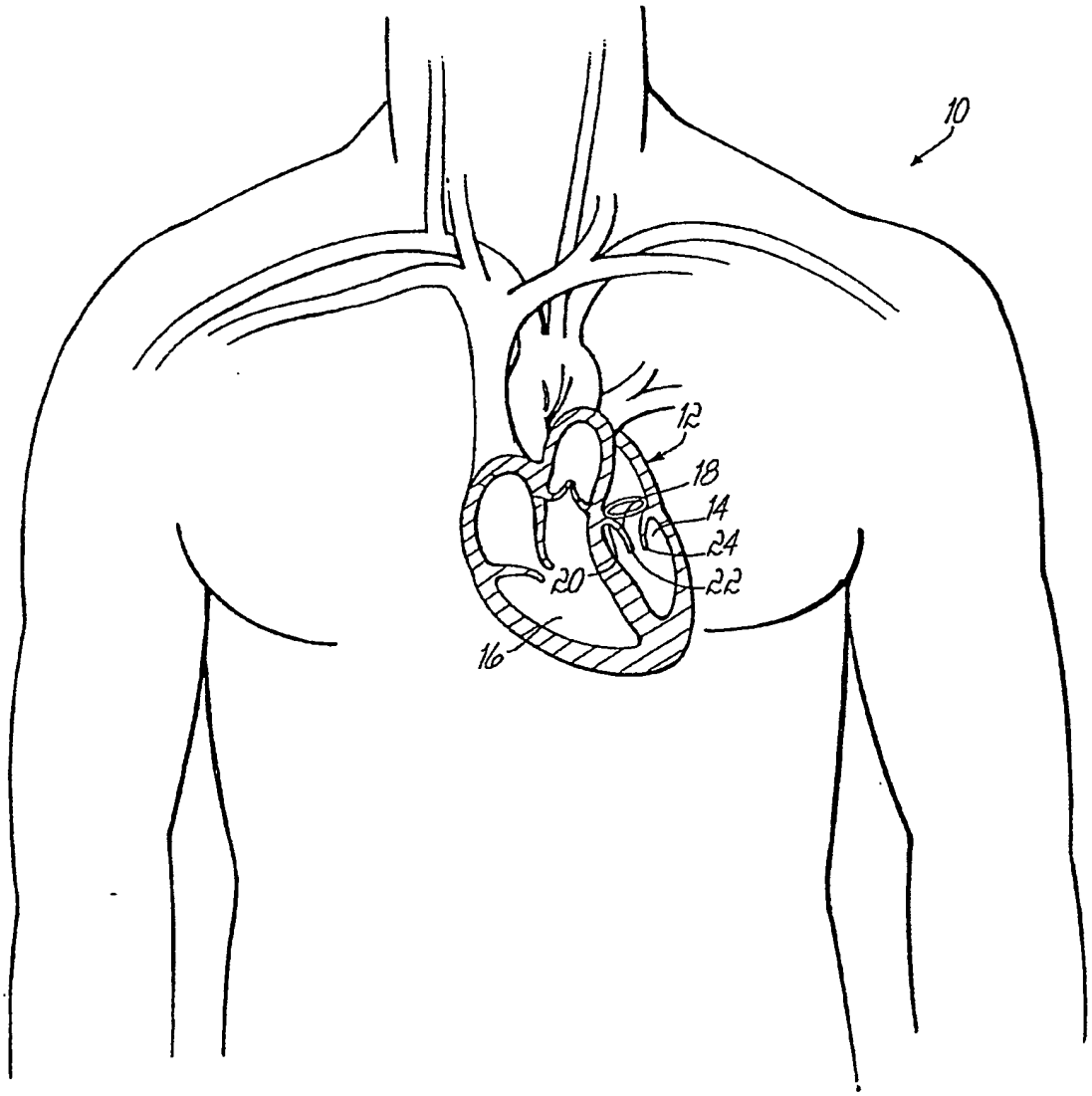

FIG. 1

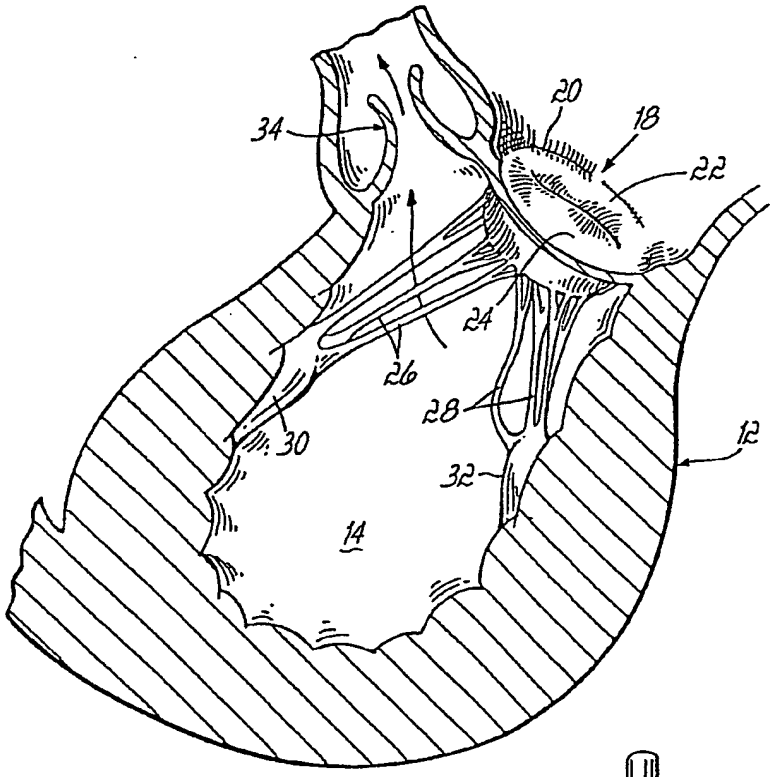

FIG. 1A

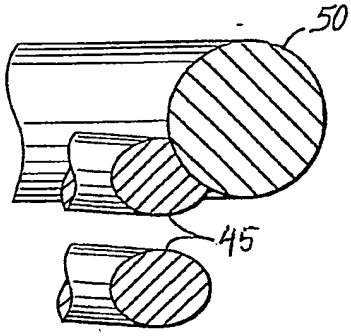

FIG. 3

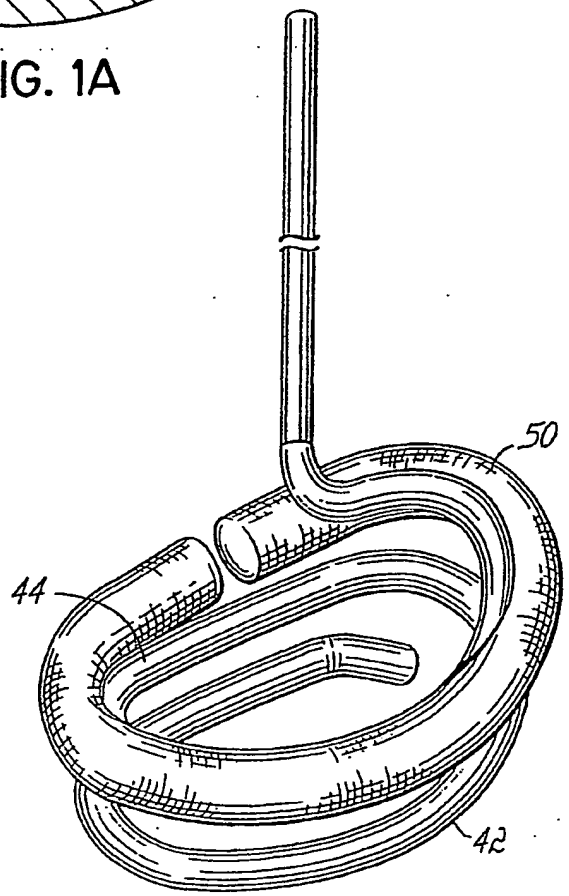

FIG. 2

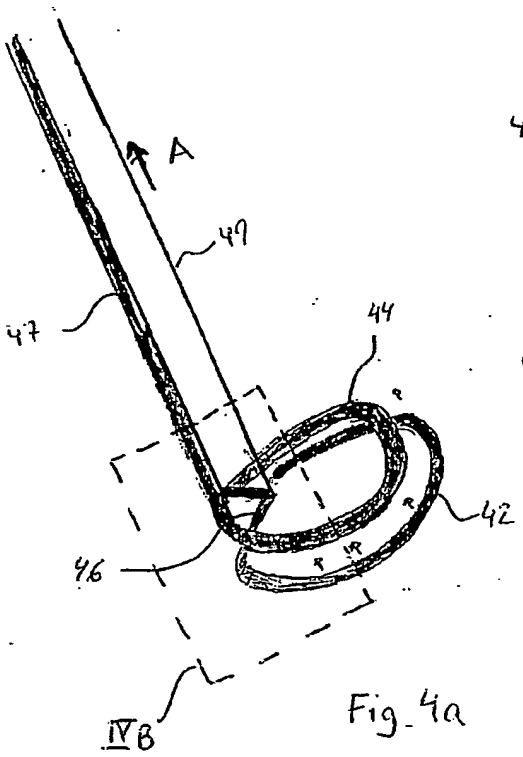

Fig 4a

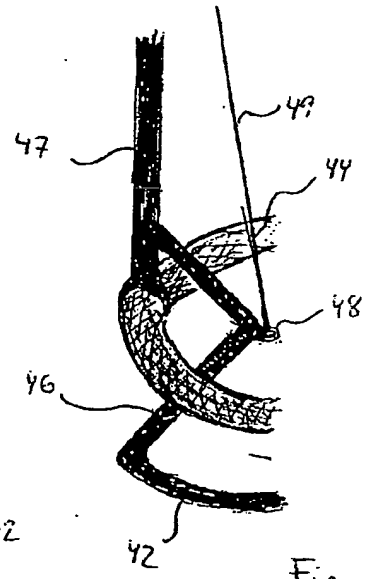

Fig 4b

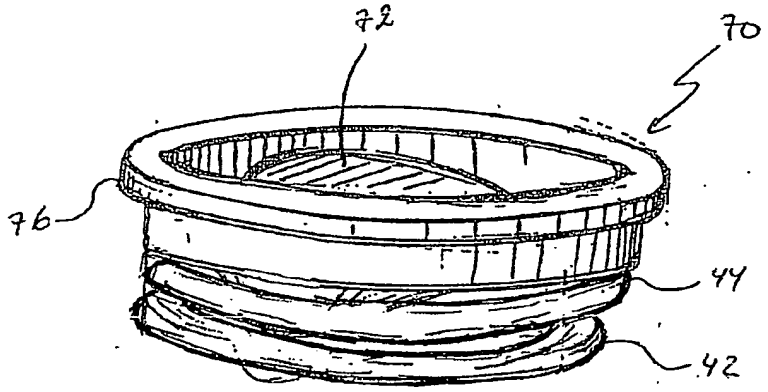

Fig 5

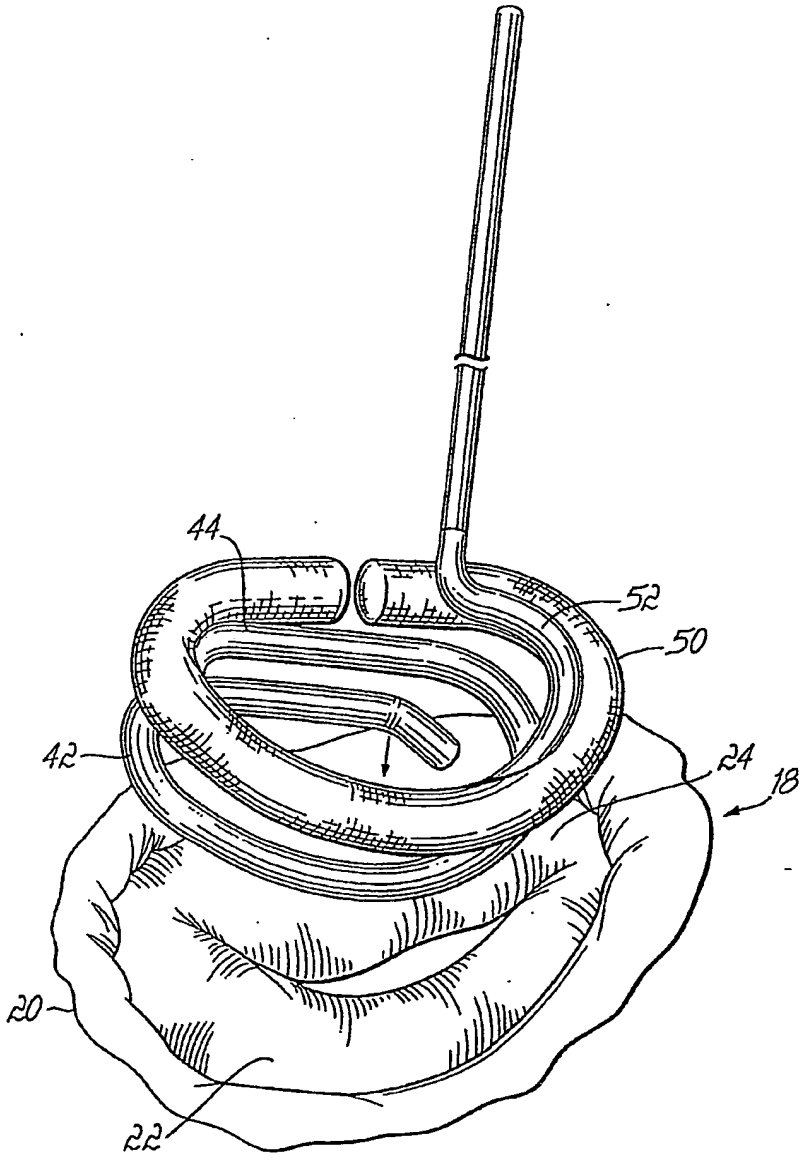

FIG. 6A

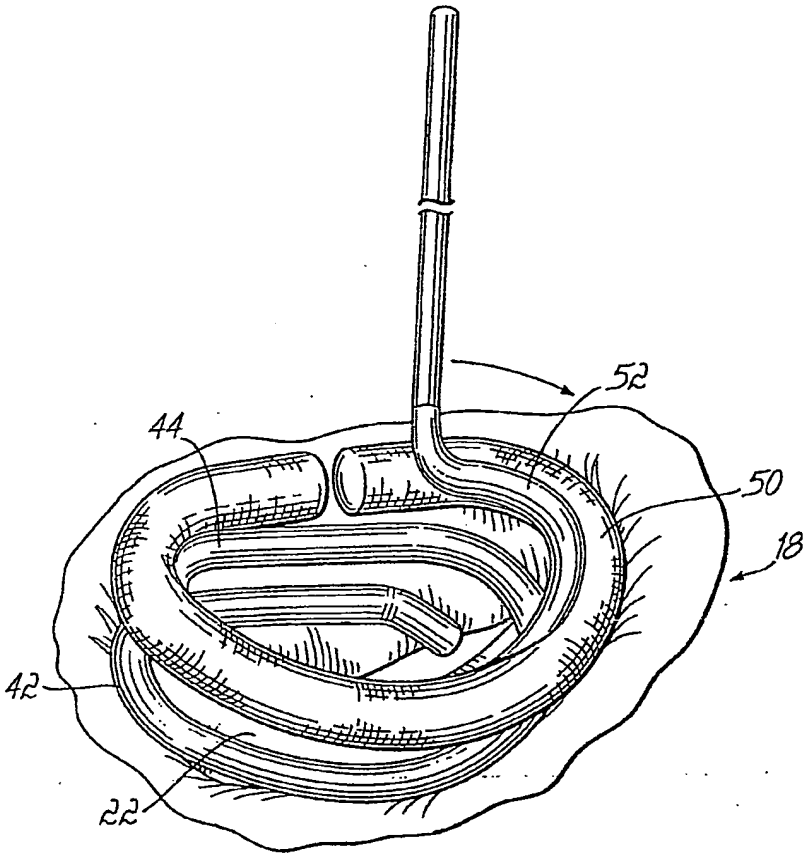

FIG. 6B

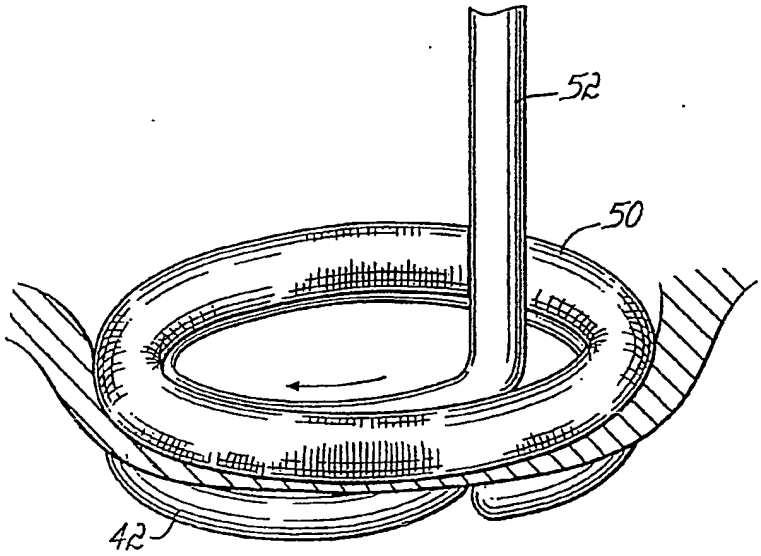

FIG. 7

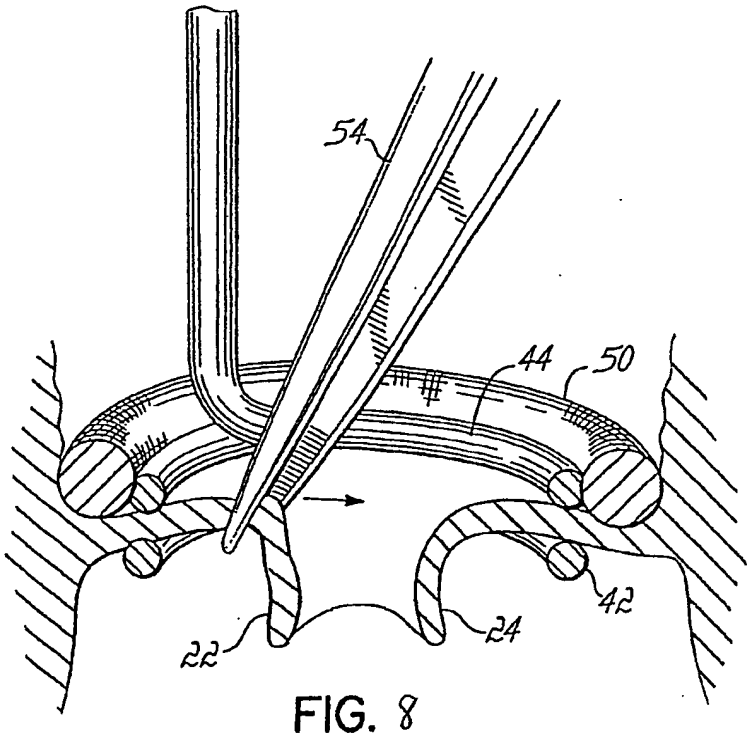

FIG. 8

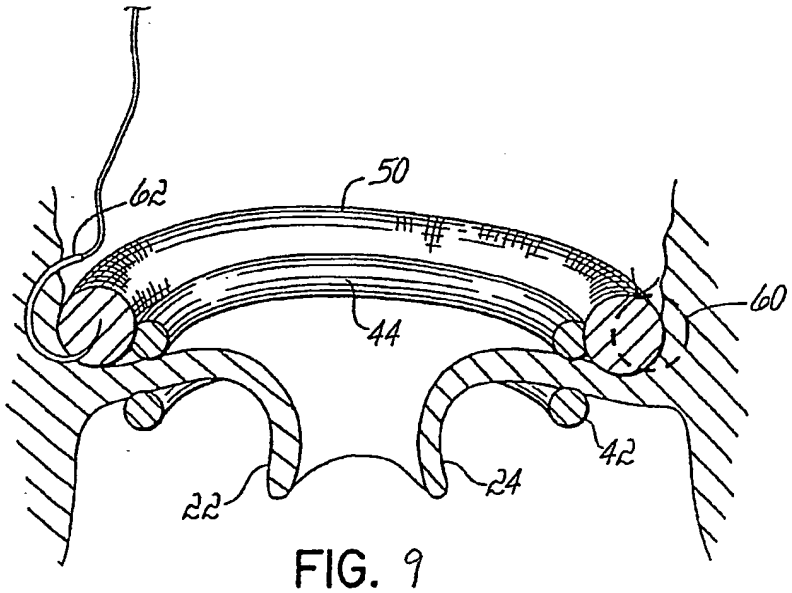

FIG. 9

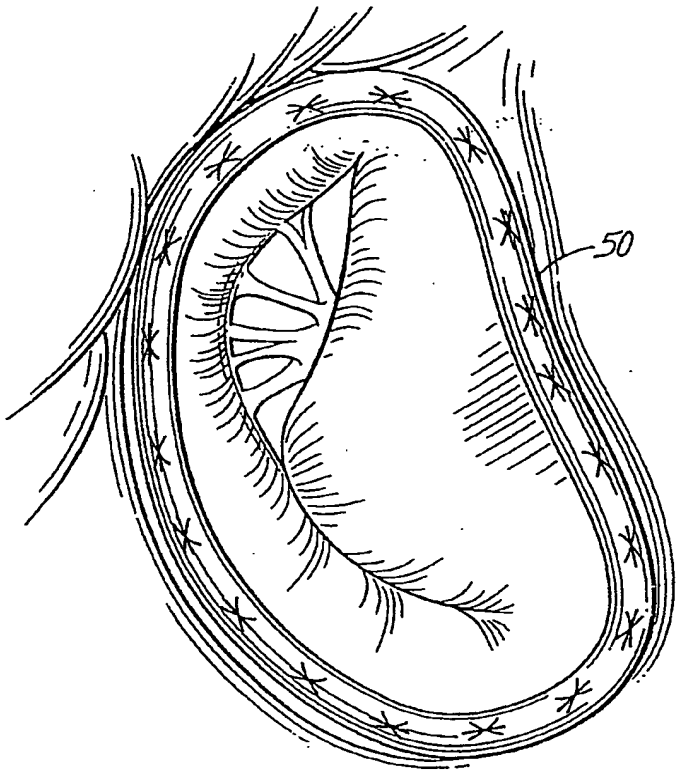

FIG. 10

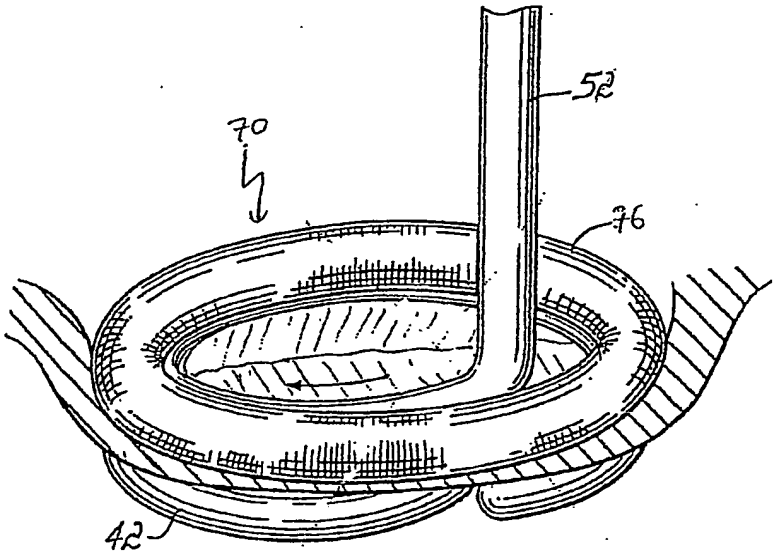

FIG. 11

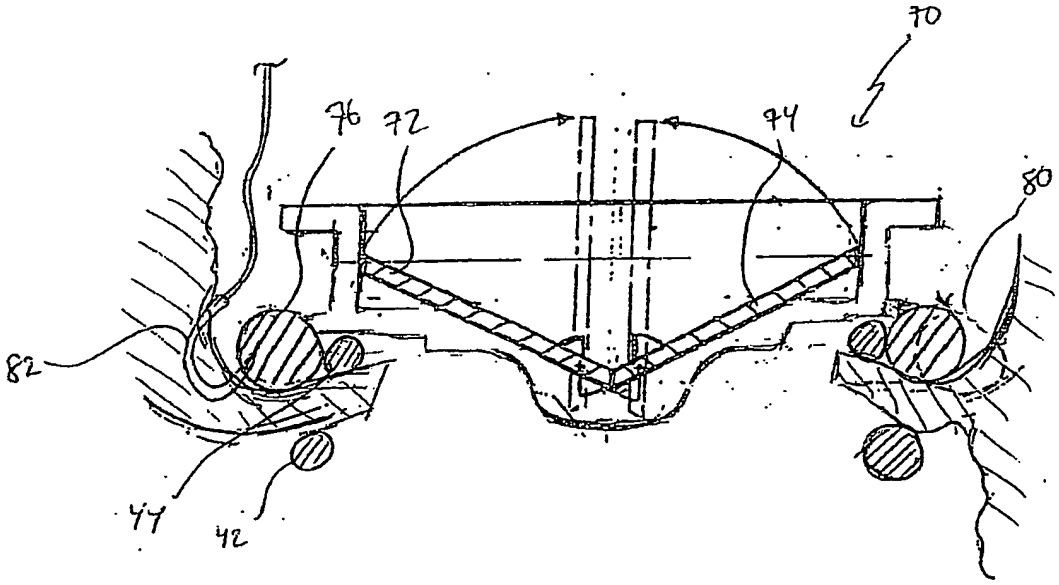

Fig 12

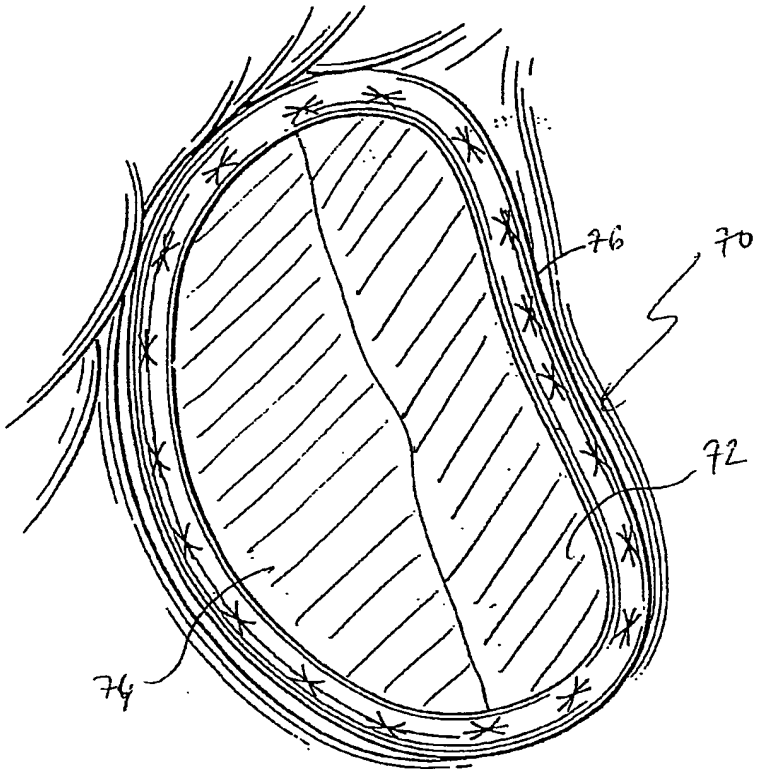

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2005/000909

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2004089250 A1 (REALYVASQUEZ, F.ET AL), 21 October 2004 (21.10.2004), figures 18-19 --	1-6,10-26
A	US 5403305 A (J.A. SAUTER ET AL), 4 April 1995 (04.04.1995) --	1-6,10-26
A	US 6406492 B1 (T.W. LYTLE), 18 June 2002 (18.06.2002), figure 3, abstract --	1-6,10-26
A	US 20020013621 A1 (R. STOBIE ET AL), 31 January 2002 (31.01.2002), figures 3-4, abstract --	1-6,10-26

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 February 2006	01-03-2006
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Brander / MRo Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2005/000909

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 20040019357 A1 (L.A. CAMPBELL ET AL), 29 January 2004 (29.01.2004), figures 2,4,5, abstract -- --------	1-6,10-26

International application No.
PCT/SE2005/000909

INTERNATIONAL PATENT CLASSIFICATION (IPC):

A61F 2/24 (2006.01)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2005/000909

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 7-9 and 27-29
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 7-9 and 27-29 relate to methods of treatment of the human or animal body by surgery or by therapy, as well as diagnostic methods (Rule 39.1(iv)).

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2005/000909

WO	2004089250	A1	21/10/2004	US	20040020837 A	05/02/2004
				US	20050107871 A	19/05/2005
				US	20050075659 A	07/04/2005
US	5403305	A	04/04/1995	NONE		
US	6406492	B1	18/06/2002	CA	2366819 A	12/10/2000
				EP	1164977 A	02/01/2002
				JP	2002540843 T	03/12/2002
				US	6689163 B	10/02/2004
				US	20020169503 A	14/11/2002
				WO	0059408 A	12/10/2000
US	20020013621	A1	31/01/2002	AU	8288501 A	13/02/2002
				BR	0112728 A	24/06/2003
				CA	2415944 A	07/02/2002
				DE	60115047 D	00/00/0000
				EP	1303234 A,B	23/04/2003
				JP	2004508852 T	25/03/2004
				US	6409758 B	25/06/2002
				US	6702852 B	09/03/2004
				US	20020161431 A	31/10/2002
				US	20040138741 A	15/07/2004
				WO	0209621 A	07/02/2002
US	20040019357	A1	29/01/2004	NONE		